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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,811	11/10/2003	Satoshi Mizutani	20050/0200482-US0	5411
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DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER HAND, MELANIE JO	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/705,811	Applicant(s) MIZUTANI ET AL.	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,11 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,11 and 13-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>see Other</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDSs: 1/18/08, 1/29/08, 1/30/08, 2/8/08, 4/29/08, 7/18/08.</u> |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed July 18, 2008 have been fully considered but they are not persuasive. With respect to arguments regarding claim 1: Applicant argues beginning on page 12 of the Remarks that Osborn does not teach or suggest first and second crossover point geometry as recited in amended claim 1 because Osborn does not teach or suggest one or more slits arranged to cross one another and does not disclose or suggest crossover points arranged both along a centerline of the interlabial device and between the centerline and a peripheral edge of the interlabial pad. This is not persuasive because Osborn discloses the following: The absorbent interlabial device 20 may also be constructed with a plurality of slits in the main absorbent portion 22 so as to permit bending of the product in multiple independent directions. Such a structure allows the product to more easily respond to the stresses associated with body movements...The top surface of the structure may also have one or more slits or have other regions of preferred bending..." (Col. 15, lines 19-34) The slits permit bending and permit such bending in multiple independent directions. This cannot be accomplished without slits that extend in multiple independent directions and Osborn is certainly suggesting that the slits are present throughout the entire top and absorbent portions. Thus Osborn certainly suggests one slit extending along the centerline so that pad bends to fit symmetrically and correctly within the user's labia. Osborn also fairly suggests slits between the centerline and peripheral edges of the pad in multiple directions, thus fairly suggesting crossover points both along the centerline and between the centerline and a peripheral edge of the pad.
2. Applicant's arguments with regard to independent claim 17 and dependent claims 3, 5, 11, 13-16, 18 and 19 have been fully considered but are not persuasive, as applicant's

arguments depend entirely on arguments regarding the rejection of claim 1, which have been addressed *supra*.

Information Disclosure Statements

3. The information disclosure statements (IDS) submitted on the following dates: January 18, 2008, January 29, 2008, January 30, 2008, February 8, 2008, April 29, 2008, and July 18, 2008, were filed after the mailing date of the non-final action on January 9, 2008. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 3, 5, 11 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osborn, III et al (U.S. Patent No. 5,891,126).

With respect to **claim 1**: Osborn teaches an interlabial pad 20 with a size, weight, and flexibility capable of being held between labia by pinching a part or the whole portion of the interlabial pad naturally therebetween, having a first axis that is substantially parallel to an anteroposterior axis of a wearer, and a second axis included in a horizontal plane when the wearer is standing and which is perpendicular to the first axis, comprising: an absorbent body 22 for absorbing body fluid, the absorbent body 22 having a plurality of bending elements including a slit formed on a surface of the absorbent body 20 with a prescribed length and depth, the bending elements being provided in a prescribed position of the absorbent body with a smaller bending strength compared to positions other than the prescribed position, in order to make the absorbent body easy to bend into a U-shape (Fig. 8, Col. 15, lines 19-22); and a coating material 42 enclosing the absorbent body 22, and maintaining an effect of the bending elements, the coating material 42 surrounding the absorbent body 22 and thus defining a main form of the interlabial pad 20 (Fig. 4) (Col. 12, lines 16-25), wherein a surface of the coating material 42 is not provided with the slit-like processing; the bending elements are formed of bending element pieces defined by a slit and the immediate area adjacent the slit, in which the slit is extended for the length of the pad 20, and the bending element pieces are vertical bending element piece of absorbent body 22 when the body 22 is in the use configuration shown in Fig. 8, those vertical bending element pieces being extended substantially parallel with said second axis, the vertical bending element pieces are pieces of absorbent body 22 (Fig. 4) One of the bending elements is formed in a bending element piece in which the slit is extended, the bending element piece including a vertical bending element piece that is extended in a direction that is substantially parallel to the

second axis. (Col. 15, lines 19-34) The one vertical bending element piece of absorbent body 22 when the body 22 is in the use configuration shown in Fig. 8 has a plurality of slits, one of which is arranged cross a center line which lies along the first axis of the interlabial pad 20. The bending elements are formed of a bending element piece in which the slit is extended; and the bending element piece is a parallel bending element piece being extended substantially parallel with the first axis, since the slits which define the areas of the bending element pieces also extend substantially parallel with said first axis. Parallel bending element pieces can be arranged near the center line of the interlabial pad 20, which lies along said first axis of the interlabial pad, as evidenced by the ability of the pad body to bend about axes parallel to said first axis as shown in Fig. 8. The bending elements are formed of a bending element piece in which the slit is extended. The configuration of the absorbent body 22 seen in Fig. 8 is evidence of the presence of bending element pieces that reach the peripheral side edges of the absorbent body. The bending element is formed of a bending element piece (indicated generally at 26,28 in Fig. 4) in which the slit is extended, and the bending element piece is positioned in the direction of the second axis, halfway between a center part positioned near the center line (indicated generally at "L" in Fig. 1) of the interlabial pad and the peripheral edges of the interlabial pad 20, and extends for a prescribed length that is substantially parallel with the first axis. (Figs. 1,4) The bending element is formed of a bending element piece in which the slit is extended because the bending piece is also comprised of absorbent body 22; and the absorbent body 22 of the interlabial pad comprises a plurality of the bending element pieces being extended for a prescribed length in a state where the pieces are positioned substantially parallel with each other. The bending element is formed of a first bending element piece and a second bending element piece when the pad 20 is in use configuration as seen in Fig. 8, in which the slit is extended in both the first bending element piece and the second bending

element piece; a second bending element piece that is extended for a second prescribed length and that is substantially parallel with the first axis in its X dimension (Fig. 1), and is positioned near the center line of the interlabial pad 20; and the first bending element piece and the second bending element piece cross each other near the center line of the interlabial pad 20. (Figs. 1,4)

Osborn does not explicitly teach that the absorbent body 22 has a shape that is any of the shapes set forth in claim 1. However, since Osborn teaches that the body 22 may have an ovoid shape, and a gourd-planar shape is considered herein to be generally oval in shape, it would be obvious to one of ordinary skill in the art to modify the article of Osborn such that the absorbent body has a gourd-planar shape with a reasonable expectation of success to ensure that the absorbent body still properly fits between the labia of the user.

Osborn does not explicitly teach that such slits that are arranged substantially parallel to one another are arranged so that, when the absorbent body is extended flat, the plurality of bending element pieces appear to be in a checkboard pattern. However applicant has not establish sufficient criticality for such a checkerboard arrangement. The criticality that exists in the disclosure states the following: "Compared with arrangements in which the bending elements are placed parallel lengthwise, such arrangement has narrower intervals of the bending element pieces, consequently, it is considered that the flexural rigidity of the whole interlabial pad will be reduced evenly. Also, the flexural rigidity of the whole interlabial pad can be adjusted properly by changing the length of the bending element pieces." (Specification, Page 22, ¶1) Applicant provides no quantitative evidence or change in inherent property of the claimed pad that is altered as a direct result of arranging the bending elements in a staggered (considered herein to include checkerboard) arrangement and is comparing the staggered arrangement with arrangements in which the bending elements are placed parallel lengthwise. Alternate rows of bending elements in a staggered arrangement as is depicted in Fig. 8 also

exhibit a lengthwise parallel configuration with each other, therefore Examiner believes there is no material difference between the staggered (including checkerboard) arrangement of bending elements claimed and the general placement of a plurality of slits taught by Osborn. However, applicant has identified the arrangement as a result effective variable, as slit arrangement in the prior art device of Osborn would be as well, thus it would be obvious to one of ordinary skill in the art to further arrange the slits taught by Osborn in a checkerboard pattern.

Osborn does not explicitly teach slits or first bending element pieces that extend parallel to said second axis and that are positioned to cross the center line (indicated generally by "L" in Fig. 1) of the interlabial pad 20, which lies along said first axis. However applicant has not established sufficient criticality for such an arrangement. The criticality that exists in the disclosure states the following: "Compared with arrangements in which the bending elements are placed parallel lengthwise, such arrangement has narrower intervals of the bending element pieces, consequently, it is considered that the flexural rigidity of the whole interlabial pad will be reduced evenly. Also, the flexural rigidity of the whole interlabial pad can be adjusted properly by changing the length of the bending element pieces." (Specification, Page 22, ¶1) Applicant provides no quantitative evidence or change in inherent property of the claimed pad that is altered as a direct result of arranging the bending element pieces in such an arrangement, However, since applicant has identified the arrangement as a result effective variable, as slit arrangement in the prior art device of Osborn would be as well, it would be obvious to one of ordinary skill in the art to further arrange the slits taught by Osborn in such a way as to have first bending element pieces (slits) parallel to the "Y" direction denoted in Fig. 1 and second bending element pieces parallel to the "X" direction denoted in Fig. 1.

With respect to **claim 3**: Each slit has a length of 3 to 30 mm and a breadth of 5 mm or less, and a distance between each parallel adjacent slit is 3-20 mm. Osborn teaches that the slits facilitate bending of body 22 in independent directions (Col. 15, lines 19-22), thus the slits must extend substantially the entire length of body 22, which is between 35-100 mm (Col. 6, lines 28-33), which overlaps the relevant range in claim 3. The entire width of body 22 in the “Y” direction, shown in Fig. 1, is 2-7 mm (Col. 11, lines 27-34), thus the slits necessarily have a width that is 5 mm or less. Similarly, the distance between each parallel slit is also no greater than the width of the body 22, i.e. 2-7 mm, which overlaps the range of 3-20 mm.

With respect to **claim 5**: The bending elements are formed of a bending element piece in which the slit is extended; and a plurality of the bending element pieces are arranged in a line that is symmetrical with respect to the center line of the interlabial pad 20, which lies along the first axis of the interlabial pad 20.

With respect to **claim 11**: The bending element is formed of a bending element piece in which the slit is extended, and wherein the bending element is positioned near the center line of the interlabial pad.

Osborn does not teach that said bending element piece extends in a V-shape towards the peripheral edges of the absorbent body from the second axis at a prescribed angle. (Fig. 2) However applicant has not established sufficient criticality for such an arrangement. The criticality that exists in the disclosure states the following: “Compared with arrangements in which the bending elements are placed parallel lengthwise, such arrangement has narrower intervals of the bending element pieces, consequently, it is considered that the flexural rigidity of the whole interlabial pad will be reduced evenly. Also, the flexural rigidity of the whole interlabial

pad can be adjusted properly by changing the length of the bending element pieces.”

(Specification, Page 22, ¶1) Applicant provides no quantitative evidence or change in inherent property of the claimed pad that is altered as a direct result of arranging the bending element pieces in such an arrangement. However, since applicant has identified the arrangement as a result effective variable, as slit arrangement in the prior art device of Osborn would be as well, it would be obvious to one of ordinary skill in the art to further arrange the slits taught by Osborn in such a way as to have first bending element pieces (slits) parallel to the “Y” direction denoted in Fig. 1 and second bending element pieces parallel to the “X” direction denoted in Fig. 1.

With respect to **claim 13**: The bending element includes a low-density portion defined by the void spaces created between adjacent folds of body 22 nearest coating material; 42 and between the folds and the coating material 42. (Fig. 4)

With respect to **claim 14**: An opposite side surface 20B to a body of the interlabial pad 20 taught by Osborn comprises a mini sheet piece which is provided over one side part 24 to another side part 24, wherein both side parts 24 are substantially parallel to the first axis of the interlabial pad 20 (Fig. 1); and a finger insert hole (Fig. 8) is formed between the mini sheet piece 24 and the opposite side surface 20B to the body.

With respect to **claim 15**: The interlabial pad 20 is a pad for an incontinence of urine. (see Abstract)

With respect to **claim 16**: The interlabial pad 20 is a pad for catamenial purposes, i.e. absorbing vaginal discharge. (see Abstract)

With respect to **claim 17**: Osborn teaches a method of adjusting a form flexibility used for an interlabial pad 20 with a size, weight, flexibility capable of being held between labia by a part or the whole portion of the interlabial pad 20 being naturally inserted therebetween, having a first axis X that is substantially parallel to an anteroposterior axis of a wearer, and a second axis included in a horizontal plane when the wearer is standing and which is perpendicular to the first axis X, comprising: an absorbent body 22 for absorbing body fluid and a coating material 42 for enclosing said absorbent body 22, the absorbent body 22 defining a main form of the interlabial pad (Fig. 4); and a bending element including a slit formed with a prescribed length and depth, provided in a prescribed position of the interlabial pad 20 (specifically the absorbent body 22) with a lower bending strength compared to a part other than the prescribed position owing to the proximity of the bending element to the slit serving as a bending axis, wherein the method comprises the step of: adjusting the form flexibility of the interlabial pad 20 by a bending element application method using the bending element. (Fig. 8, Col. 9, lines 38-47) The lower bending strength is present in order to make the absorbent body easy to bend into a U-shape along the first axis. The one vertical bending element piece of absorbent body 22 when the body 22 is in the use configuration shown in Fig. 8 has a plurality of slits, one of which is arranged cross a center line which lies along the first axis of the interlabial pad 20. The bending elements are formed of a bending element piece in which the slit is extended; and the bending element piece is a parallel bending element piece being extended substantially parallel with the first axis, since the slits which define the areas of the bending element pieces also extend substantially parallel with said first axis. Parallel bending element pieces can be arranged near the center line of the interlabial pad 20, which lies along said first axis of the interlabial pad, as evidenced by the ability of the pad body to bend about axes parallel to said first axis as shown in Fig. 8. The

bending elements are formed of a bending element piece in which the slit is extended. The configuration of the absorbent body 22 seen in Fig. 8 is evidence of the presence of bending element pieces that reach the peripheral side edges of the absorbent body. The interlabial pad according to claim 1, wherein the bending element is formed of a bending element piece (indicated generally at 26,28 in Fig. 4) in which the slit is extended, and the bending element piece is positioned in the direction of the second axis, halfway between a center part positioned near the center line (indicated generally at "L" in Fig. 1) of the interlabial pad and the peripheral edges of the interlabial pad 20, and extends for a prescribed length that is substantially parallel with the first axis. (Figs. 1,4) The bending element is formed of a bending element piece in which the slit is extended because the bending piece is also comprised of absorbent body 22; and the absorbent body 22 of the interlabial pad comprises a plurality of the bending element pieces being extended for a prescribed length in a state where the pieces are positioned substantially parallel with each other. The bending element is formed of a first bending element piece and a second bending element piece when the pad 20 is in use configuration as seen in Fig. 8, in which the slit is extended in both the first bending element piece and the second bending element piece; a second bending element piece that is extended for a second prescribed length and that is substantially parallel with the first axis in its X dimension (Fig. 1), and is positioned near the center line of the interlabial pad 20; and the first bending element piece and the second bending element piece cross each other near the center line of the interlabial pad 20. (Figs. 1,4)

Osborn does not explicitly teach that such slits that are arranged substantially parallel to one another are arranged so that, when the absorbent body is extended flat, the plurality of bending element pieces appear to be in a checkboard pattern. The slit arrangement in the prior art device of Osborn is considered herein to be a result-effective variable, as the arrangement

affects the flexibility of the article and the amount of surface area available for absorption of exudate, thus affecting the absorption capacity of the article. It would be obvious to one of ordinary skill in the art to further arrange the slits taught by Osborn in a checkerboard pattern with a reasonable expectation of success to provide substantially equal amounts of absorptive area and slit area, as a checkerboard pattern of slits would, to provide a balance of absorptive capacity and flexibility. It has been held that the discovery of an optimum value of a result-effective variable in a known process is ordinarily within the skill of the art. See *In re Boesch and Slaney*, 205 USPQ 215 (C.C.P.A. 1980)

Osborn does not explicitly teach slits or first bending element pieces that extend parallel to said second axis and that are positioned to cross the center line (indicated generally by "L" in Fig. 1) of the interlabial pad 20, which lies along said first axis. However applicant has not established sufficient criticality for such an arrangement. The criticality that exists in the disclosure states the following: "Compared with arrangements in which the bending elements are placed parallel lengthwise, such arrangement has narrower intervals of the bending element pieces, consequently, it is considered that the flexural rigidity of the whole interlabial pad will be reduced evenly. Also, the flexural rigidity of the whole interlabial pad can be adjusted properly by changing the length of the bending element pieces." (Specification, Page 22, ¶1) Applicant provides no quantitative evidence or change in inherent property of the claimed pad that is altered as a direct result of arranging the bending element pieces in such an arrangement, However, since applicant has identified the arrangement as a result effective variable, as slit arrangement in the prior art device of Osborn would be as well, it would be obvious to one of ordinary skill in the art to further arrange the slits taught by Osborn in such a way as to have first bending element pieces (slits) parallel to the "Y" direction denoted in Fig. 1 and second bending element pieces parallel to the "X" direction denoted in Fig. 1.

With respect to **claim 18**: The bending element application method comprises the step of changing more than one of the form (by compression against the inner walls of the labia), number (from zero to at least one), positioning area (squatting or adjusting position of pad 20 along the labia of a user), and arrangement (to a "T" shape) of the bending element. (Fig. 8, Col. 9, lines 38-47)

With respect to **claim 19**: The first bending element pieces taught by Osborn inherently and necessarily have the slit positioned between the center line of the absorbent body 22 and the first peripheral edge of the absorbent body, as the slits are present on the surface of the absorbent body and are positioned at a boundary between an extension part (the flaps 24) of the interlabial pad 20 and a long protrusion part of the interlabial pad defined by the part of the body 22 that extends parallel to the second (i.e. vertical) axis.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761